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10/598,026	10/18/2007	Alastair Edwin McAuley	FPHCR.112NP	9347

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EXAMINER

DIXON, ANNETTE FREDRICKA

ART UNIT	PAPER NUMBER
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3771

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/598,026	Applicant(s) MCAULEY ET AL.	
	Examiner ANNETTE DIXON	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-20, 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13-20, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to the amendment filed on June 6, 2011. Examiner acknowledges claims 1-11, 13-20, 22, and 23 are pending in this application, with claims 1, 8, 10, and 20 having been currently amended, claim 11 having been withdrawn from consideration, and claims 12 and 21 having been cancelled.

Election/Restrictions

2. This application contains claim 11 drawn to an invention nonelected with out traverse in the reply filed on January 12, 2011. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Objections

3. Claim 8 is objected to because of the following informalities: The term "secoond" appears to be misspelled. Examiner has interpreted the term to be "second"; however, appropriate correction and clarification is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 1-11, 13-20, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, Claim 1 recites the limitation "said humidified gases"; however, there is insufficient antecedent basis for this limitation in the claim.

Specifically, Claims 19 and 20 recites the limitation "said transportation means"; however, there is insufficient antecedent basis for this limitation in the claim.

Specifically, in Claim 19, Applicant asserts that the claim element "transportation means" is a limitation that attempts to invoke 35 U.S.C. 112, sixth paragraph. However, it is unclear whether the claim element invokes 35 U.S.C. 112, sixth paragraph, because it is unclear whether the recited structure, material, or acts are sufficient for performing the claimed function further, Applicant has not provided clear linking structure which defines what is meant by the term "transportation means". If applicant wishes to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant may:

(a) Amend the claim to include the phrase "means for" or "step for". The phrase "means for" or "step for" must be modified by functional language, and the phrase or term must **not** be modified by sufficient structure, material, or acts for performing the claimed function; or

(b) Present a sufficient showing that the claim limitation is written as a function to be performed and the claim does **not** recite sufficient structure, material, or

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acts for performing the claimed function to preclude application of 35 U.S.C. 112, sixth paragraph. For more information, see MPEP § 2181.

Specifically, in Claim 20, Applicant asserts that the claim element “humidification means” is a limitation that attempts to invoke 35 U.S.C. 112, sixth paragraph. However, it is unclear whether the claim element invokes 35 U.S.C. 112, sixth paragraph, because it is unclear whether the recited structure, material, or acts are sufficient for performing the claimed function further, Applicant has not provided clear linking structure which defines what is meant by the term “humidification means”. If applicant wishes to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant may:

(a) Amend the claim to include the phrase “means for” or “step for”. The phrase “means for” or “step for” must be modified by functional language, and the phrase or term must **not** be modified by sufficient structure, material, or acts for performing the claimed function; or

(b) Present a sufficient showing that the claim limitation is written as a function to be performed and the claim does **not** recite sufficient structure, material, or acts for performing the claimed function to preclude application of 35 U.S.C. 112, sixth paragraph. For more information, see MPEP § 2181.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1 and 23 are rejected under 35 U.S.C. 102 (b) as being anticipated by Papania et al. (WO 02/074372).

As to Claims 1 and 23, Papania discloses a breathing assistance apparatus, comprising: a nasal cannula (Figures 1-3, and 4A-4D, specifically portion 54) shaped to fit within a user's nares (Page 14, Lines 21 and 22) and adapted to deliver gases to a user (via 8, Page 14, Lines 11-17), wherein the nasal cannula (54) includes at least one prong (54) that is capable of increased flow of gases and creates a positive airway pressure in the user's airway, the at least one prong (54) having an opening at its end (via pathway 60, Figures 4A and 4B) formed in a plane that is oriented at an angle with respect to a transverse plane, the transverse plane being transverse to the longitudinal axis of the prong (54) extending from the opening (via pathway 60, Figures 4A and 4B), such that in use, gases (via 8, Page 14, Lines 11-17) flowing through the prong (54) are directed to the user's nasal passages (Page 14, Lines 21 and 22).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. Claims 1-10, 13-20, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ziaee (6,644,315) in view of Papania et al. (WO 02/074372).

As to Claims 1 and 23, Ziaee discloses a breathing assistance apparatus, comprising: a nasal cannula (Figure 1, specifically portions 24), shaped to fit with a user's nares (Column 4, Lines 33-67) to deliver gas to a user, wherein the nasal cannula (Figure 1, specifically portions 24) include at least one prong (24) that is capable of increased flow delivery of gases and creates a positive airway pressure in the user's airway, such that in use, gases flowing through said prongs are directed to user's nasal passages. Ziaee discloses nasal prongs (24) that are removable (Column 4, Lines 33-67). Yet, Ziaee does not expressly disclose or teach the shape of the removable nasal prongs to having an opening at its end formed in a plane that is oriented at an angle with respect to a transverse plane, the transverse plane being transverse to the longitudinal axis of the prong extending from the opening. Papania teaches a removable nasal prong (54) having an opening at its end (via pathway 60, Figures 4A and 4B) formed in a plane that is oriented at an angle with respect to a transverse plane, the transverse plane being transverse to the longitudinal axis of the prong (54) extending from the opening (via pathway 60, Figures 4A and 4B) for the purpose of preventing backflow of gases. (Page 14, Line 11 thru Page 15, Line 14). Therefore, it would have been obvious to one having ordinary skill in the art to modify the shape of the removable nasal prongs to include an opening with a transverse plane as taught by Papania for the purpose of preventing backflow of gases.

As to Claim 2, the modified Ziaee discloses loops (35) on the nasal cannula (Figure 1) to secure a head strap. (Column 3, Lines 49 and 50).

As to Claim 4, the modified Ziaee discloses a flange (the upper portion of 23 connecting to the prong 24) near the end of the prong (24); additionally, the prong discloses a flange region (the corrugated rings at the end of 24) for connecting to the upper portion of element 23. (Figure 1 and Column 4, Lines 33-67).

As to Claims 5, 6, 8-10, and 13-14, the modified Ziaee discloses duplicate prongs (24) which are ovular in shape (circular) for contouring to the nares. (Column 4, Lines 33-67).

As to Claims 7, 16, 17, and 22, the modified Ziaee discloses the prongs (24) are flexible for sealing engagement with the patient's nasal passages, where the stepped or corrugated rings (Column 4, Lines 48-67) engage the nostrils for leak free connection. (Column 4, Lines 33-67).

As to Claim 15, the modified Ziaee discloses the prongs (24) are angled towards each other. (Figure 3) by the upper portion of element 23.

As to Claim 18, the modified Ziaee discloses a vent hole (57) in the nasal cannula and another set of vent holes (208, Figure 13) for venting exhaust gas.

As to Claim 19, as best understood by the Examiner, the modified Ziaee discloses the nasal cannula (Figure 1) is connected to the transportation means by a swivel connection having a flange (the claimed socket), and a circular portion (the claimed ball). (Column 6, Lines 4-67).

As to Claim 20, as best understood by the Examiner, the modified Ziaee, specifically, Papania teaches the application of aqueous solutions (specifically medications) with the gas for the administering active medications to the patient. (Abstract).

Response to Arguments

10. Applicant's arguments with respect to claim 1-11, 13-20, 22, and 23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNETTE DIXON whose telephone number is (571)272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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